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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,642 01/29/2004 Scott P. Steinmann 630666.91179 5403

26710 7590 03/28/2007

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/767,642

Applicant(s)

STEINMANN, SCOTT P.

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Attachment 1,2

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-6, and 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Rauscher et al. (US 6,887,277 B2). Rauscher discloses a prosthesis (see fig.11) comprising a stem (5+35), a head (33) having an outer wall (thickness of head) defining an interior space (19), wherein the head (33) may be placed over the stem end (35) adapted for transverse and axial movement (flexible head is compressible, allowing movement in multiple directions), the outer wall of the head having *at least one* opening (see fig.11), a screw (34) arranged in each opening adapted to contact the end of the stem and secure the head by constraining axial and transverse movement (see fig.11; col.4, lines 60-65), wherein each opening is in a lateral direction to the stem axis (seen in fig.11 as perpendicular to the stems longitudinal axis) and an interior surface of the head wall is spaced from and end of the stem (fig.12 and 13 show cross sectional views of the spaces between the stem 9 and head 15; shown is the actual implant, and the trial is disclosed

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to be more movable, thus inherently has more space between the components in order to orient and fix in the correct position; col.4, lines 60-65). Replacement of a radial head is intended use language, the head of Rauscher is capable of replacing a radial head.

Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (US 6,428,577 B1). Evans discloses a prosthesis (10) comprising a stem (tibial tray; 18+13+17), a head (insert 28) having an outer wall (exterior surface) defining an interior space (opening 33), wherein the head (28) may be placed over the stem end (end may be considered 18) adapted for transverse and axial movement (see fig.6), the outer wall of the head having at least one opening (33), a screw (24) arranged in each opening (33) adapted to contact the end of the stem (18) and secure the head (28) by constraining axial and transverse movement (seen secured in fig.7), wherein each opening (33) is in a lateral direction to the stem axis (fig.6 shows the opening having an axis extending laterally with respect to the stem axis; see attachment 1) and an interior surface of the head wall is spaced from and end of the stem (seen in both figs.6,7). Evans head (28) is elliptical (fig.1) and concave in shape (see fig.5, 6, 7). Replacement of a radial head is intended use language, the head of Evans is capable of replacing a radial head at the elbow joint.

Claims 1, 2, 5, 6, 8, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Callaway et al. (US 2002/0120339 A1). Callaway discloses a prosthesis (see figs.3a-5c) comprising a stem (12), a head (18) having an outer wall (24, 22) defining an interior space (cavity 22), wherein the head (18) may be placed over the stem end (12) adapted for transverse

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and axial movement (see figs), the outer wall of the head having *at least one* opening (see figs; throughhole in 18), a screw (20) arranged in each opening adapted to contact the end of the stem and secure the head by constraining axial and transverse movement (fig. 5a-5c), wherein each opening is in a lateral direction to the stem axis (fig. 5b opening extends laterally to axis; see attachment 2) and an interior surface of the head wall (22) is spaced from and end of the stem. Replacement of a radial head is intended use language, the head of Callaway is capable of replacing a radial head.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rauscher et al. (US 6,887,277 B2). Rauscher discloses a prosthesis having a stem and head adapted to be secured onto the stem by an opening/screw connection (see above). Rauscher however discloses only one opening/screw (34 in fig. 11) instead of three as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have three openings instead of three, since the result would be merely further security and a duplication of the original parts. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Claims 1-6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terrill-Grisoni et al. (US 6,361,563 B2, cited in IDS). Terrill-Grisoni discloses a modular

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prosthesis for the head of the radius at the elbow joint substantially as claimed. Terrill-Grisoni discloses a prosthesis (2.11) comprising a stem (2.15; fig.13, 14), a head (2.13; fig.7-10) having an outer wall (2.19) defining an interior space (2.27), wherein the head (2.13) may be placed over the stem end (2.15) adapted for transverse and axial movement, the outer wall of the head having *at least one* opening (2.53), and a connector (2.47) arranged in each opening adapted to contact the end of the stem and secure the head by constraining axial and transverse movement (fig.37), wherein each opening is in a lateral direction to the stem axis (2.53, see fig.8) and an interior surface of the head wall is spaced from an end of the stem (fig.37). Terrill-Grisoni does not disclose the connector however, to be a screw, but a spring instead. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to use screws instead of springs, as such would merely constitute a substitution of functional equivalents (providing the same function of securing).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

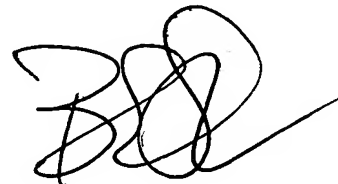
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER

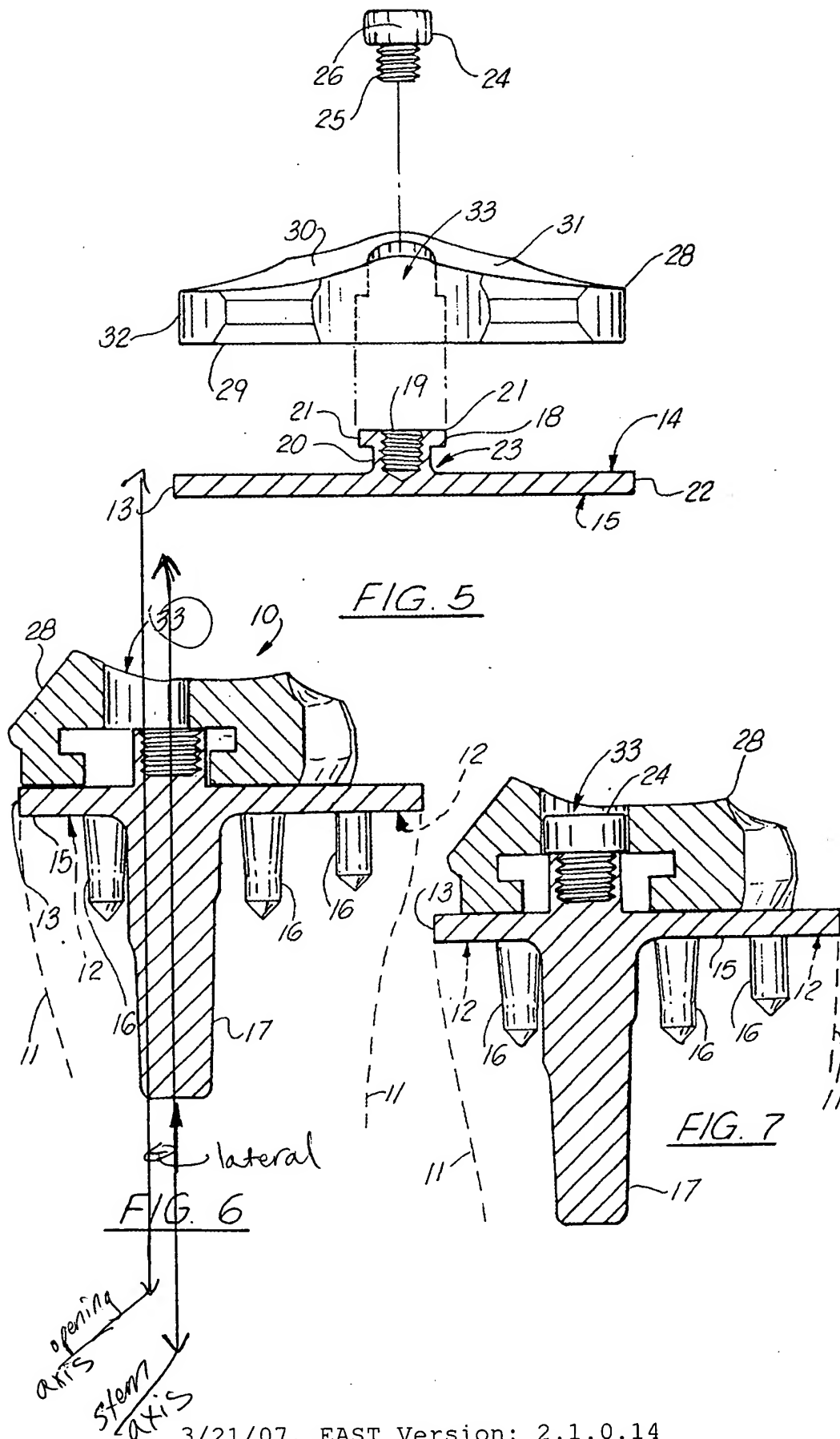
Attachment #1 (marked up)

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US 6,428,577 B1



Attachment #2 (marked up)

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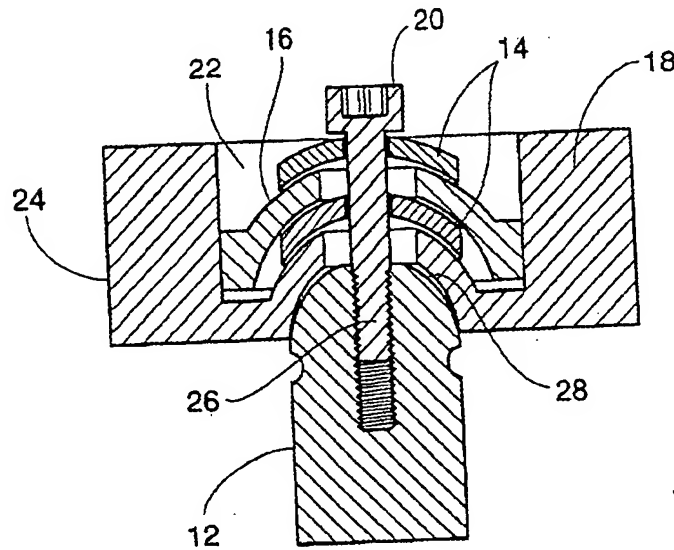


Fig. 5a

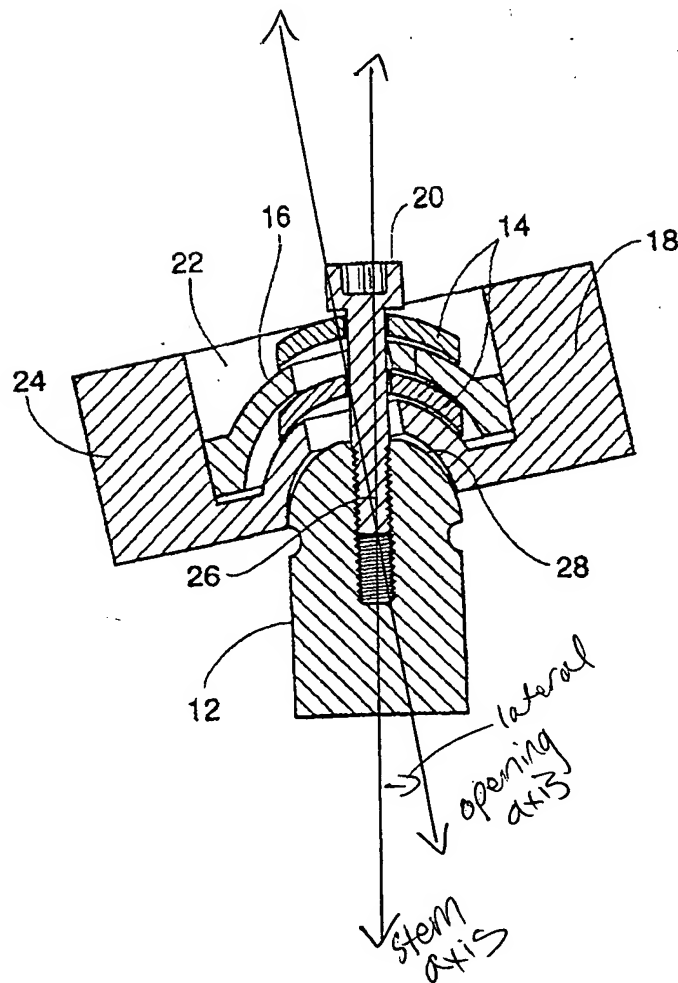


Fig. 5b